# DEMONSTRATION PROTOCOL

## General Guidance

This protocol provides a common basis for technology evaluation and certification by the Cal/EPA staff. The General Guidance protocol sets forth the program's principles on performance claims, data quality, testing, and more.

CALIFORNIA ENVIRONMENTAL TECHNOLOGY CERTIFICATION

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STATE OF CALIFORNIA

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

# California Environmental Protection Agency (Cal/EPA)
# California Environmental Technology Certification Program

# General Acceptance Criteria and Standards Guidance for the Verification of Environmental Technologies

## A. Introduction

This document sets forth the general principles that should be applied in the certification of environmental technologies under the jurisdiction of the Cal/EPA. This document is supplemented by a quality system management plan and, as necessary, documents containing technology-sector specific acceptance criteria and verification process guidance.

### *1. Definitions*

"*Verification*" shall mean the authentication of evidence; the act of reviewing, inspecting, testing, auditing, or otherwise establishing and documenting to determine whether performance claims by the proponent are based on scientifically sound principles and supported by sound data, and whether items, processes, services, or documents regarding the performance of a technology conform to the stated performance claims and whether other necessary attributes of the technology conform to expectations that are customary and reasonable for the intended use(s).

"*Certification*" shall mean a ministerial act by Cal/EPA in which Cal/EPA asserts the verified and/or expected performance of a technology together with any conditions and limitations that may apply to its use, and specifies the period of time for which the assertion is intended to be valid.

"*Technology*" shall mean the total of (1) equipment and/or materials, (2) the knowledge and/or skill for proper application, and (3) quality systems applicable to manufacture and use. If either equipment or materials by themselves are the subject of verification, the verification shall be for specified uses.
"Environmental benefit of a technology" shall mean risk reduction, conservation of natural resources, or both.

"*Efficacy*" of a technology shall mean its ability to perform an intended function, whether or not addressed in a proponent's claim and whether other necessary attributes of the technology conform to expectations that are customary and reasonable for the intended use(s).

"*Reliability*" of a technology shall mean its ability to meet a stated performance claim(s) and other necessary attributes over time, meeting reasonable expectations regarding service life, maintaining performance levels and throughput, and lack of downtime. Consideration is given to instructions or recommendations to the user for carrying out preventive maintenance, periodic maintenance offered by the vendor, user's ability to detect malfunctions and to take corrective action in case of malfunctions.

"*Protectiveness*" is the level of control of hazards to the operator(s), the general public, and the environment from the operation of the technology. And from emissions, discharges, or residues resulting from its use.

"*Quality System*" is a system of assuring the quality of producing the technology, its equipment and supplies, and items procured from other sources (quality management system in effect at the manufacturer's level). In addition it includes quality assurance measures to be taken by the user to assure proper operation, as set forth in user manuals, other instructions, and operator training provided by the manufacturer. Also a system for assuring the quality of data produced in verification.

"*Proponent*" is the applicant (manufacturer, vendor) presenting the technology for verification/certification. Synonymous with "technology holder."

"*Verification Entity*" shall mean an entity that is independent of the proponent and is specifically authorized by Cal/EPA to conduct technology verifications according to the principles set forth in this document (see Section (c) below).

"*High professional competence*" or "*highest professional standards*" means that the data or results of a study (technology evaluation) are accepted by other technical experts.

"*Independence*" shall mean the absence of financial or other material interest in the success or failure of a technology evaluation in combination with the technical competence to carry out assigned parts or all of an evaluation.

## *2. Applicability*

a. The provisions of this document should apply to duly authorized technology verification (certification, pre-certification) activities undertaken by Boards and Departments of Cal/EPA (in the following referred to as Cal/EPA).

b. The guidance contained in this document should also apply to bodies which Cal/EPA would deem qualified to carry out technology verifications or specialized tasks as part of a verification (hereinafter referred to as "verification entities").

c. Cal/EPA, after administrative review and subject to the criteria set forth below, may accept as valid technology verifications performed by other certification bodies or jurisdictions provided that the other entity has been found by Cal/EPA to evaluate performance claims according to principles that are no less stringent than set forth in this document, and after execution of a document stating acceptance of the other entity's standards by Cal/EPA. For

the purpose of this paragraph, administrative review means a review by Cal/EPA of a verification or certification performed by the other entity to determine acceptability under California laws and regulations, to conduct a review for conformity with the provisions of this document, to make a certification decision, and/or to determine limitations and restrictions that would apply to a Cal/EPA certification. Not included in this review is additional verification work (obtaining and evaluating additional technical data) necessary to meet Cal/EPA certification requirements.

### *3. Verification Entities*

Verification entities are entities that are bound by agreement with Cal/EPA to conduct verifications in one or several technical fields in which they can provide the technical expertise necessary to carry out assigned parts or all of the evaluation. In carrying out verifications, each verification entity should be required to observe the acceptance criteria and process standards set forth in this document and in similar technology-sector specific documents that Cal/EPA has issued or may issue. The verification entity should employ professional staff committed to the principles set forth in this document, retain experts familiar with the principles and applications of the technology to be verified, and maintain a quality management system acceptable to Cal/EPA. The entity should be committed to due diligence, integrity, and highest professional standards. The entity should maintain confidentiality with regard to proprietary information and be free from conflict of interest with respect to technologies undergoing verification. Cal/EPA's agreement with the entity should specify that patentable matter arising from verification-related activities will be treated in a manner that, on a case-by-case basis, is agreed upon by both the proponent and Cal/EPA. Cal/EPA may stipulate additional terms in its agreements with verification entities.

## B. Acceptance Criteria

1. Cal/EPA should consider for verification/certification only environmental technologies capable of providing one or more stated environmental benefits. Cal/EPA may give preference to technologies that are highly innovative or offer a superior environmental benefit.

2. At the time of verification, technologies should be available in at least one full-scale implementation and either in channels of commerce or ready for commercialization. Proponents should indicate attempts or success at verification by another entity.

3. The Proponent should be required to have control over the technology, especially its quality aspects, through outright ownership, patents, franchise, or other license.

## C. Verification Process Guidance

### *1. Quality Standard*

a. Cal/EPA and its verification entities should adhere to the quality standards set forth in ANSI/ASQC Document E4 (Ref. 3, 1995 or more recent versions). Cal/EPA and its verification entities should adopt quality management plans which, among other items, establish and document the methodology and levels of peer review and internal approvals that apply before a verification report is finalized and a certification issued.

b. From time to time and as necessary, Cal/EPA should prepare technology-specific guidance documents ("protocols") that set forth the acceptance criteria and process standards for the evaluation of certain groups, types, or categories of technologies. Each such protocol should be subject to internal and external technical and stakeholder review before publication.

### *2. Reports*

Cal/EPA or the verification entity should document each evaluation in a verification report, a public document. Verification reports should include a concise description of the technology, its underlying scientific, engineering, and operating principles (except information furnished under terms of confidentiality), a description of the necessary components, the range of conditions for operation, and the environmental conditions under which the technology operates. Furthermore, the evaluation report should describe the methodology employed in the evaluation and the findings, conclusions, and the basis for the conclusions. It should contain a recommendation to certify or not to certify the technology. If appropriate, proposed certification language should state the limitations and restrictions to be applied to the certification. Verification entities should be required to provide, upon request by Cal/EPA, data and other documentation on which these conclusions and recommendations are based.

### *3. Performance Claims and Scope of Evaluation*

a. Proponents should be required to state specific claims regarding a technology's efficacy, performance, and other critical attributes of the technology, reliability, protectiveness, and quality aspects in manufacture or use.

b. Proponents' performance claims should be specific, quantitative, and verifiable through appropriate experimentation and accepted statistical methods. Claims should not refer to named brands or trademarks except those held by the proponent. If a performance objective is to meet a specific regulatory standard, reference to the standard or a copy of the standard should be included. The performance claim should also indicate the intended range of application of the technology and the operating and environmental conditions for which the claim is intended to be valid. Cal/EPA may issue criteria for specifying performance claims. If a proponent's performance claims do not address critical attributes such as reliability, protectiveness, or quality systems, Cal/EPA or the verifying entity should strive to evaluate the technology with regard to these attributes against criteria that are reasonable and customary for the intended use(s) of the technology.

c. If a verification entity or a certifying body other than Cal/EPA does not include one or several of these critical attributes in an evaluation, or a significant aspect of such a critical area is not addressed, or quality standards have not been met, Cal/EPA, in consideration of these omissions, may determine that the verification is incomplete and refer the matter back to the verification entity or certification body with a statement of deficiencies.

d. If the omissions are so minor so as not to place the certification in question, Cal/EPA may accept the verification to the extent that relevant claims and attributes have been successfully evaluated under accepted standards of quality, issuing a certification with the appropriate disclaimers and limitations. If another certifying body carried out the verification, Cal/EPA may propose to the proponent to carry out or supervise the additional evaluation.

e. If a verification by another verification entity or jurisdiction is found incomplete, Cal/EPA should make a determination to certify with the appropriate disclaimers and/or limitations, or not to certify, or carry out the necessary additional work with the proponent’s concurrence and at the proponent’s expense.

### *4. Scientific and Engineering Basis*

a. Verifications should include evidence that the technology is based on sound scientific and engineering principles as documented in the peer-reviewed scientific literature, or documented in reports written for review by technical experts, or determined to be sound on the basis of professional judgment. The technology should be designed and manufactured from materials to ensure that it is reliable. For treatment technologies, the proponent should present an expected mass balance of inputs and outputs, energy and water balances, and process flow diagrams, is strongly encouraged.

### *5. Data Produced by Independent Bodies*

a. Verification requires that performance data be obtained by independent entities. For each evaluation Cal/EPA should determine for independence of each participating testing organization, verification entity, and external reviewer.

### *6. Proponent's In-House Validation Data, Product Development Record (Data that have not been independently collected or verified)*

a. Cal/EPA or the verification entity may request and accept data sets generated by the proponent in-house in advance of, or during the verification. These data sets may be used in assessing proponent's awareness of underlying scientific principles, proponent's awareness of sound engineering design, proponent's awareness of operating and environmental conditions appropriate for the technology, and proponent's awareness of quality assurance principles in manufacturing and servicing the technology, and to develop hypotheses for verification (i.e., independent) testing. Proponent-generated data sets should be evaluated for completeness. Proponent-generated data sets should be clearly identified and discussed separate from independently generated data sets.

### *7. Verification Practices, Data and Data Quality, Statistical Significance*.

a. Due diligence and highest professional competence should be applied in all verifications and all studies that are part of a verification.

b. Operating conditions during verification should be representative of the intended uses of the technology and consistent with the performance claim(s) to be verified. Samples should be taken using documented methods and under a quality system consistent with Section C.1.a. Samples taken should be representative of the operation of the technology and taken in adequate numbers to allow interpretation by generally accepted statistical methods. Chain-of-custody procedures should be followed. Operating conditions during the verification testing should be monitored and documented. Documentation should address unforeseen events and measures taken.

c. Verifications should be based on complete data sets. Required completeness (in per cent of samples to be taken) should be stated in the work plan in advance of the verification testing. Findings of completeness should be included in the evaluation report.

d. All testing methodology applied by the proponent or verification entity should be recognized by standard-setting, governmental or consensus organizations or should either be peer reviewed for scientific soundness or documented in a form suitable for review by technical experts. The data or measurements generated during testing should be of sound quality and achieve data quality objectives consistent with the purpose(s) of the verification. If the data were not generated using a documented quality system or Quality Assurance Project Plan (QAPP), an independent data assessment should be performed.

e. Testing laboratories should be accredited by a competent certifying body or inspected by qualified auditors for the purpose of the intended study. Testing results should be reported together with documentation of QA/QC procedures and their results. Testing laboratories should be strongly encouraged to participate in appropriate proficiency (round-robin) studies in relevant fields of testing and the results made a part of the evaluation record.

f. Field testing of a technology should be either full-scale or on a scale that is determined field-relevant by the certifying body.

g. In the evaluation of treatment technologies, a mass balance approach should be used wherever possible. Inputs and outputs, end- and byproducts, emissions, residuals, and energy use should be clearly stated. Conditions that may interfere with the proper operation of the technology or may result in adverse discharges should be stated to the extent that they are known or can be reasonably anticipated.

h. Statistical significance of a technology's conformance with a stated performance claim (or reasonable expectation of the technology's performance) should be at the 95% level of confidence unless stated otherwise. The selection of a level of significance, or level of confidence, may be guided by considerations of the risk or the cost associated with a technology's failure. The rationale for such an approach should be stated in the evaluation report.

### *8. Knowledge and Skills as Necessary Components of a Technology*

Knowledge and skills that are necessary for the operation of a technology should be stated by the proponent and the evaluated for reasonableness. This includes user training and customer support.

### *9. Reliability Considerations*

a. If reliability considerations are included in the verification, Cal/EPA or the Verification Entity should review existing records of operation, if available. The proponent should furnish recommended monitoring schedules and guidance to the user regarding the early detection of malfunctions and corrective actions. These should be included in the evaluation. Where applicable, warranties, guarantees and similar documents should also be reviewed to evaluate the proponent's claim(s) on technology reliability.

### *10. Protectiveness Considerations*

a. In evaluations of protectiveness, Cal/EPA or the Verification Entity should evaluate the operator safety, the potential for endangerment, including toxic exposure, of the general public, and potential effects on the environment. Proponents should make available for evaluation and to each user all relevant Material Data Safety Sheets (MSDSs), Health and Safety Plan, Emergency Response Plans, and specifications of protective equipment.

### *11. Quality Systems (Proponent's and User's)*

a. Proponent should declare intent and ability to maintain the quality of the technology as verified. Companies holding certification under ISO-9000 (or equivalent) should submit the appropriate certificate(s). Proponent should furnish a reasonably detailed description of the quality system that is in place to maintain the technology at the standard of quality at which it was certified. Such quality system should be subject to audit by Cal/EPA.

b. The proponent should report all quality control measures, calibrations, and monitoring required of the user to operate the technology to meet specified claims and expectations regarding reliability and protectiveness.

### *12. References*

International Organization for Standardization. "General Requirements for the Competence of Calibration and Testing Laboratories." ISO/IEC Guide 25, 1990.

U.S. Federal Trade Commission. "Guides for the Use of Environmental Marketing Claims."16CFR Part 260, October 4, 1996.

American Society for Quality Control, Energy and Environmental Quality Division, Environmental Issues Group. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQC E4. Washington, D.C.: American National Standards Institute, 1995.

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